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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/535,390 | 03/24/2000 | Balaram Ghosh | U 012673-3 | 2390 |

140 7590 06/04/2002

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| EXAMINER |
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KWON, BRIAN YONG S

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| ART UNIT | PAPER NUMBER |
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1614

DATE MAILED: 06/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/535,390

Applicant(s)

GHOSH ET AL.

Examiner

Brian S Kwon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2002.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 2-8 and 14-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 9-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of Application

By amendment filed April 3, 2002, Claim 2 has been amended and Claims 9-17 have been newly added. However, the amended claim 2 that is directed to a method for monitoring septic shock conditions and the newly added claims 14-17 that are directed to a method for controlling neutrophil infiltration during inflammatory conditions are considered not fully responsive to the originally examined invention that is directed to a method of treating septic shock conditions. Therefore, Claims 2-8 and 14-17 are withdrawn from further consideration by the examiner as being drawn to non-elected invention.

Summary of Action

- I. The specification is objected to because of the spacing of the lines of the specification (in page 8, lines 23-24) should be double lines.
- II. The rejection of claim 1 under 35 USC 102(b) as being anticipated by Aggarwal (WO 970877) will be maintained for the reason of the record.
- III. Claims 9-13 are rejected under 35 USC 103(a) as being unpatentable over Aggarwal (WO 9709877) in view of Schneider (US 6013273).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 USC 102(b) as being anticipated by Aggarwal (WO 970877).

This rejection is analogous to the original rejection as being anticipated by Aggarwal.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 9-13 are rejected under 35 USC 103(a) as being unpatentable over Aggarwal (WO 9709877) in view of Schneider (US 6013273).

Aggarwal teach a use of curcumin in treating septic shock, wherein said curcumin is administered in a dose of from about 1mg/kg to about 100mg/kg (page 1, line 21 thru page 2, line 2; Claims 1 and 3).

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Schneider et al. (US 6013273) teaches the use of antioxidant in treating septic or endotoxin shock (column 4, lines 51-53).

The teaching of Aggarwal differs from the claimed invention in 1) combination with an antioxidant preparation (claim 13); 2) preventing neutrophil infiltration from blood vessels to underlying tissues (claim 9) ; 3) oral administration (claim 9); 4) and the specific time intervals (claim 9).

To incorporate such teaching into the teaching of Aggarwal, would have been obvious in view of Schneider et al. who teaches the use of antioxidant in treating septic shock.

Above references in combination make clear that curcumin and antioxidant have been individually used for the treatment of septic (or endotoxin) shock. It is obvious to combine two compositions each of which is taught by prior art to be useful for same purpose; idea of combining them flows logically from their having been individually taught in the prior art. The combination of active ingredient with the same character is merely the additive effect of each individual component. *See In re Kerkhoven, 205 USPQ 1069 (CCPA 1980).*

Above references in combination make clear that the combination of curcumin and antioxidant for the treatment of septic shock is old and well known. One having ordinary skill in the art would have been motivated to do so such that such combination provides enhanced activity in treating septic shock while minimizing adverse effects.

The prior art does not disclose the underlying pharmacological mechanism of “preventing neutrophil infiltration from blood vessels to underlying tissues”. However, the fact that the applicant may have discovered a new pharmacological mechanism for curcumin is not

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considered patentably distinctive over the prior art which are directed to the same therapeutic application (for the treatment of septic shock condition).

The prior art does not disclose the specific time interval requirement for the initial and subsequent dose of curcumin. However, differences in time interval requirements will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such time periods is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable time periods by routine experimentation.

In addition, the determination of dosage form having optimum therapeutic index is well considered within the skill of the artisan, and the artisan would be motivated to determine optimum dosage form to get the maximum effect of the drug.

Response to Arguments

Applicant's arguments filed April 3, 2002 have been fully considered but they are not persuasive.

Applicant's argument takes position that applicant's discovery of the activity of curcumin in "the prevention of neutrophil infiltration leading to prevention of septic shock" is novel and important part of the finding wherein the inventors provide evidence for the first time. The examiner agrees that none of prior art cited by the examiner specifically discloses the underlying pharmacological mechanism of "preventing neutrophil infiltration from blood vessels to underlying tissues". However, the fact that the applicant may have discovered a new

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pharmacological mechanism for curcumin is not considered patentably distinctive over the prior art that is directed to the same therapeutic application (for the treatment of septic shock condition).

Conclusion

Applicant's amendment (e.g., requiring the combination of curcumin and an antioxidant preparation) necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (703)308-5377. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Brian Kwon

**ZOHREH FAY
PRIMARY EXAMINER
GROUP 1600**



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